IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
(Attorney Docket No. 8970.95081)

In re U.S. Patent Application of Antrim	)	
Application No.: 10/601,912	)	Group Art Unit: 1623
Filed: June 23, 2003	)	Examiner: Layla Bland
For: DEXRINIZED, SACCHARIDE-DERIVED OLIGOSACCHARIDES	)	Confirmation No. 7581

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

REPLY TO EXAMINER'S ANSWER

This is a reply to the Examiner's Answer mailed October 25, 2010.

In maintaining her rejection over the cited references, the Examiner misreads the references and misinterprets the claimed invention, and focuses on the wrong claim elements. The references she cites will be addressed in turn.

Saleeb

This reference does not appear to disclose derivatization of a carbohydrate in an extruder, and appears inapposite for this reason. Moreover, Saleeb does not appear to provide that any starting component being extruded should include at least 50% dextrose as claimed. Saleeb also does not disclose that the product of extrusion is a carbohydrate product that includes some 1,2 and 1,3 bonds and a majority of 1,4 bonds.

In Saleeb, a labile material is blended in an extruder with major and minor components. The resulting product is a glass-like material in which the labile material is fixed. Saleeb teaches (col. 9) that the "set temperature of the extruder should be as low as possible," and that the zone temperatures of the extruder "are set at or below about the melting point of the major

ingredient." At these temperatures, the extrudate is a "carbohydrate glass" product. A purpose of Saleeb is to fix the labile material in this carbohydrate glass.

The Examiner's analysis of the present application re Saleeb is in error. She seizes on one sentence fragment from the instant specification – "Generally, extrusion conditions require barrel temperatures that range from about 25° to about 220°C." Based on this sentence fragment, she contends that any temperature in this temperature range, which includes temperatures as low as 25° room temperature, is sufficient to yield derivatization, and hence the temperatures of Saleeb are sufficient to cause derivatization. Specifically, she argues "Saleeb teaches extrusion of a mixture of saccharides in the presence of an acid, at a temperature which is described in the instant specification as being appropriate for the preparation of saccharide-derivatized oligosaccharides (page 10, 25°C - 220°C)."

In fact, the Examiner is misreading the specification. What the specification actually teaches is as follows:

> Generally, extrusion conditions require barrel temperatures that range from about 25° C to about 220° C, with the maximum barrel temperature more preferably in a range of about 140° to 180° C. The internal sample temperature at the dye [sic] head of the extruder can be in a range of 160° C to 275° C, but preferably remains between the range 190° to 230° C.

Contrary to the Examiner's assertion, the instant specification does not teach that derivatization will occur at temperatures as low as 25 ° C. The specification teaches that perhaps one or more zones of a multizone extruder might be set at such temperature, but the specification also teaches that the internal sample temperatures at the die head should be 160° C to 275° C. This is well above the temperatures taught by of Saleeb. Claim 35 expressly calls for this temperature range.

The Examiner has failed to demonstrate that Saleeb yields a derivatized product at all. This is not the only defect in the Examiner's reasoning, however. The claims specify a specific type of derivatized product, one that includes 1,2 and 1,3 linking bonds. Where are these teachings in Saleeb? Where are the teachings of a product with a majority of 1,4 bonds? The Examiner waves these claim elements away with one sentence: "Because the product was prepared by the same process, it would be expected to be the same product." But given the difference in temperatures, the claimed process is *not* the same process as that of Saleeb.

"In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic *necessarily* flows from the teachings of the applied prior art." *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original). Here, is it *necessarily* the case that Saleeb's temperatures lead to derivatization? This can hardly be so, when Saleeb states that the extruder temperature is "at or below about the melting point of the major ingredient."

Likewise, does Saleeb's process necessarily form 1,2 and 1,3 bonds? The fact that a certain result or characteristic *may* occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993) (reversed rejection because inherency was based on what would result due to optimization of conditions, not what was necessarily present in the prior art)

In attempting an inherency rejection, the burden is on the *Examiner*, not the applicant, to establish a prima facie case of inherency. *See* M.P.E.P. 2112. Given the differences in operating temperature between Saleeb and the teachings of the present specification – and indeed, given that Saleeb appears not to teach derivatization at all –the Examiner's inherency argument is hence wrong as a matter of law. The rejections over Saleeb must be reversed.

Porzio

The Examiner's arguments with respect to Porzio are similarly deficient. Porzio appears to disclose a glass encapsulating material that is an extrudate of a specific mixture of carbohydrates and a plasticizer. The die head temperatures disclosed in the examples of Porzio are lower than that indicated in the specification (and recited in claim 35). A temperature of 160° C, on the low end of the range of sample temperatures taught in the instant specification, is equal to 320° F. Also, Porzio uses a very specific mixture starting materials. The process of Porzio is hence not identical to the process provided in the specification.

Thus, contrary to what the Examiner states, the process of Porzio would not inherently lead to the same results as the claimed process. The Examiner concedes that "Porzio does not teach whether the product contains a majority of 1,4-bonds as well as some 1,2- and 1,3-bonds." Her only argument for Porzio is a hand-waving inherency argument – because Porzio is like

Saleeb, the process of Porzio inherently anticipates. But because Porzio teaches lower temperatures, the Examiner's inherency argument is wrong. Again, in "relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic *necessarily* flows from the teachings of the applied prior art." *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original). The Examiner bears the burden of establishing inherency, and she cannot meet this burden here.

Okhuma

Okhuma does not describe or suggest a product in which the starting saccharide includes 50% dextrose, nor a starting material comprising a starch hydrolyzate to which additional saccharide has been added. Okhuma's starch is treated with hydrochloric acid, and the resulting product is extruded. There is no teaching or suggestion of the dextrose content of this starting material, and no suggestion of adding additional saccharide to a hydrolyzed starch.

We presented these arguments in our opening brief, and the Examiner has not responded to them. She ignores the salient claim limitations completely in her response. Instead, she points to teachings of two examples of Okhuma that happen to have 1,4 bonds. But where are the teachings of "said mixture of maltooligosaccharides comprising a starch hydrolyzate to which additional saccharide has been added"? Where are the teachings of "said saccharide product comprising at least 50% dextrose"? Okhuma would have to teach these elements, too, for the reference to anticipate. The Examiner has overlooked these claim elements.

Myers

This rejection is premised on a misreading of the claims. The Examiner is mistaken when she asserts "The instant claims do not require a majority of 1,4 linking bonds in the absence of other linkages," and "the broadest reasonable interpretation of the claims includes 1,4 linking bonds contained within a 1,2,4 linkage." The Examiner is wrong. The claims do indeed contemplate a majority of 1,4 linkages as determined individually. In other words, the presence of another carbohydrate linked otherwise would mean that the linkage is not a 1,4 linkage, but would be another type of linkage (1,2,4-, 1,3,4-, or 1,4,6-linkage).

This reading of the claims is compelled by the teachings of the specification, which provides (p. 11), "The majority of the bonds will be subject to enzymatic hydrolysis." A 1,4 linkage is subject to enzymatic hydrolysis, as the specification teaches. On the other hand, other forms of linkages, as evidenced by the literature from the manufacturer of FIBERSOL itself, are not subject to enzymatic hydrolysis.

The Examiner's reading of the claims is contrary to the specification. Also, her attempt to justify this analysis with reference to the Fouache reference is without merit. She states that "[a]s illustrated by the Fouache reference as mentioned by Appellant, this [counting a 1,2,4 bond as a 1,4 bond] is a reasonable and art-recognized way of counting bonds." It is irrelevant that there are multiple ways to count bonds. The teachings of other references cannot be read to contravene the teachings in the specification (the "majority of the bonds will be subject to enzymatic hydrolysis"). *See C.R. Bard, Inc. v. U.S. Surgical Corp.*, 388 F.3d 858, 862 (Fed. Cir. 2004) (holding that extrinsic evidence is less reliable than the intrinsic evidence in construing the claims).

The Examiner's rejection over Myers is based on this misreading of the claims. The Examiner appears to agree that the FIBERSOL product has almost no digestibility and hence does not include a majority of 1,4 linkages as claimed (that is presumably why the product is called "fiber"-sol). The Examiner states "A product having a 1,4 linkage contains a 1,2 linking bond and a 1,4 linking bond." (see page 11 of the Examiner's Answer). Again, this is wrong. The FIBERSOL digestibility data indicates that this product does not include a majority of 1,4 linkages as claimed. In any case, even if FIBERSOL contains "a 1,2 linking bond and a 1,4 linking bond" as asserted by the Examiner, this is still insufficient to reach the claims. If a product contains "a 1,2 linking bond and a 1,4 linking bond," this says nothing about the number of 1,4 bonds relative to 1,2 bonds.

Fouache

In our opening brief, we demonstrated that the Examiner was miscounting the bonds of Fouache, and that Fouache does not meet the claims with respect to the counting of 1,4 linkages. The Examiner offers no response, and appears to concede that we were correct in our opening brief.

Instead of responding to our argument, the Examiner focuses on another limitation of the claims. But, again, all claim limitations must be met for a reference to anticipate. When the claim is considered as a whole, Fouache does not anticipate, for the reasons stated in our opening brief.

Stahl

The Stahl reference is irrelevant and the Examiner's continued reliance on Stahl is puzzling. Where the claimed product is very substantially different from the prior art - in this case, because the claimed product has different types of bonds and a different distribution of linkages - the cited art cannot be the basis of the claimed rejections.

Stahl discloses carbohydrates that have been modified with various enzymes. As earlier discussed, enzymatic reactions of the type disclosed by Stahl are extraordinarily *specific*. They produce carbohydrates and related byproducts of a distinct, characteristic profile. In contrast, although general trends may be maintained, the specificity of bacterial reaction is not possible in an extruder. The profile of products prepared in accordance with the present teachings are markedly different from an enzymatically produced product.

The Examiner has suggested that the specification of an extruder is "broad," leading to an undefined product. To the contrary, the use of extruder would of necessity produce a product with a different carbohydrate profile than the *leuconostoc-catalyzed* reaction of Stahl. In response, the Examiner points to another bacterial species of Stahl, and asserts (without support) that this bacterium would lead to production of principally 1,4-linked carbohydrates. But again, given the specificity of bacterial reactions, the product is unlikely to resemble the product of an extruder.

Also, where are the teachings in Stahl of 1,2- and 1,3-linkages? The Examiner has failed to demonstrate that a bacterium would produce these linkages. Stahl is simply off the mark, and cannot support a Section 103 rejection.

In view of the foregoing, Applicants respectfully request reversal of the Examiner's rejections.

Respectfully submitted,

Date: December 27, 2010

By: /s/ /Allen Hoover/_____

Allen Hoover
Registration No. 37,354
FITCH EVEN TABIN & FLANNERY
120 South LaSalle Street
Suite 1600
Chicago, Illinois 60603
Telephone: 312/577-7000
Facsimile: 312/577-7007